EXHIBIT D

Prolift RCT
PROTOCOL 300-05-003

Notes from Meeting with Dr V Lucente and Dr M Murphy (Allentown, PA) to discuss Prolift RCT
02 February 2006.
G Scott

Attending: Dr Vince Lucente, Dr Miles Murphy, Sr Robin ? (Site co-ordinator), D Robinson, J Gauld, J Shen, C Guidry, G Scott
Circulation: S Dodd, P Jones

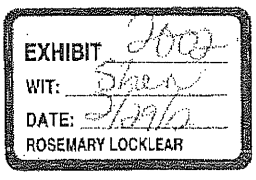
Four key issues were identified for the meeting:

- Laparoscopy vs Open for the sacrocolpopexy (SC) arm
- Standardisation of Prolift and SC
- Total vs Partial Prolift
- Other surgery

Laparoscopy vs Open
VL/MM confirmed that literature to support the equivalence of Lap vs Open is lacking. There is nothing comparing them head to head. However, there is literature to draw on such as the Lap vs Open comparison of Burch.
VL: Lap is not the dominant technique, but it will be hard to 'sell' Open SC to patients in centres where Lap is standard. However, VL was in favour of mixing Open and Lap in the control arm by use of centres, some of whom do one and some of whom do the other.
Lap and Prolfit patients can be expected to return to work in c.2weeks cf with c.6 weeks for those who had open SC.
MM: concerned about what the eventual readership will think.
VL: Outcomes are the same. Lap just involves smaller incision than open.

Standardisation of SC
MM/VL: probably should permit paravaginal repair to manage lateral defect. Reattach apically and laterally.
MM: The trial should probably permit anterior colporraphy, but not many women will have it done. VL agreed.
VL: Lap and Open SC should be the same procedure, 'suture for suture', but also got be representative of real life.
MM: Always put mesh on both sides, but tailor it to suit surgeon/patients. VL agreed.
MM/VL: Determine suture material and minimum number of sutures (probably ≥2). Most open surgeons suture to promontory, lap surgeons suture to promontory or S2/S3. Probably not an issue needing to be defined.
Sutures should be permanent, further definition is probably unnecessary.
≥4 anterior
≥6 posterior
Y-Mesh, but may be stitched as 2 parts.
Action GS to check with Reisenauer/Smith whether the two pieces of mesh each of them inserts for SC are stitched such that the second is attached to the first, effectively forming the same Y-shape as in the US (it's just that US surgeons form the Y-shape before insertion). GS to confirm that the two pieces are not separately attached to the sacrum.

Standardisation of Prolift



MM: post-hysterectomy is good.
VL: requiring Total Prolift only will lose patients. In the US there are liability issues wrt insertion of mesh that might not be required.
VL: Dyspareunia is more likely from posterior incisions
MM: If patient has had hysterectomy, then would prefer to be able to use partial Prolift (ie compartmentalised approach). If young, then more likely to use anterior only.
VL: If the trial allows compartmentalised approach then it is more like real-life.
MM: No-one will say that following a compartmentalised approach is worse than insisting on Total Prolift.
VL: Total Prolift on all cases would imply over-treating 70% of cases (I think this probably meant 70% of Stage IIs).
MM: If entry criterion is POPQ≥3, then it is OK to insist on Total Prolift; recruitment would still be adequate.
VL: Most cases are POPQ≥3
Robin: There are fair number of stage IIs.
VL: Permit entry of stage IIs, but there should be option for partial Prolift. For patients with POPQ≥3, then it is reasonable to insist on Total.
JS: When selecting investigators, we should understand their underlying preference for use of anterior, posterior and Total.

Other Surgery
MM: permitting a sling for treatment of incontinence is essential.
VL: Exclude ovarian cyst surgery or 'adnexal mass' surgery(I MISSED this and not sure what it is or whether I've got it right)
VL/MM: Everyone to have a sling inserted to treat incontinence. ≥95% of Prolift cases have or should have slings.
VL: Or make it physician discretion, but only permit it at time of trial surgery, not as separate, later procedure.

Other
Meeting Location
It was agreed that best use of travelling time would be made by hosting the Advisory Board meeting at a hotel at Paris CDG airport.
Action GS to get Ellie Craig to identify suitable hotels.

Recent Problem with Prolift
VL: Recently removed the centre of an anterior Prolift from a Tennessee woman. The device appeared to have been placed too tightly. Patient was in constant pain and had been since two weeks post surgery.
VL: Returning for surgery to deal with a bad Prolift will be a disaster. It must be fitted with slack.

Duration and Assessment Time points
VL: 1yr, 3yr, 5yr is good.

Australian Sites
VL: In order: Chris Maher, Marcus Carey, Alan Lam.

Trial Design Advice

VL: speak to David Grimes, California

Other Opinions
VL: Thinks addition of Linda Cardozo is useful. Avoid Linda Brubaker. Anne Weber would be a better dissenting voice.
MM: Bobby Shull (Correct name please) might be a better post-meeting critic.

Impact of RCT
VL: Example: the Hilton study results were too late. Faster results means greater impact. No-one knew the Hilton trial was being done, so there was no gain during its conduct.
MM: Hilton study did and still does make a difference.
VL: J&J will get credibility by doing RCT.
VL/MM: Lose credibility quickly if RCT promised and not done. Would jeopardise the whole brand

Pre-Trial Training/Experience
MM/VL: 20-30 cases needed before randomising first patient. 20 anyway to master the technique.

Anaesthesia
VL/MM: all patients have epidural, not general.

Anticipated Timings
Enrolled 30 patients to TVM in 4 months.

Endpoint
VL: composite endpoint comprised of anatomic and functional aspects should be acceptable.
Continuous management of four domains: anatomy, functional status, patient satisfaction and cost.
MM: Less certain of a composite endpoint in respect of its influence on the eventual readership.

END